DRAFT PA Criteria

Initial Approval: July 11, 2018
Revised: July 8, 2020

CRITERIA FOR PRIOR AUTHORIZATION

Type 2 Diabetes Mellitus (T2DM) Agents

~~**PROVIDER GROUP:** Pharmacy~~
BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES: ~~All dosage forms of the medications listed in Table 1 below will require prior authorization.~~ Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Canagliflozin (Invokana®)
Canagliflozin/Metformin (Invokamet®, Invokamet® XR)
Dapagliflozin (Farxiga®)
Dulaglutide (Trulicity®)
Dapagliflozin/Metformin (Xigduo XR®)
Dapagliflozin/Metformin/Saxagliptin (Qternmet XR®)
Dapagliflozin/Saxagliptin (Qtern®)
Empagliflozin (Jardiance®)
Empagliflozin/Linagliptin (Glyxambi®)
Empagliflozin/Linagliptin/ Metformin (Trijardy XR®)
Empagliflozin/Metformin (Synjardy, Synjardy XR®)
Ertugliflozin (Steglatro™)
Ertugliflozin/Metformin (Segluromet™)
Ertugliflozin/Sitagliptin (Steglujan™)
Exenatide (Bydureon®, Bydureon® BCise)
Exenatide (Byetta®)
Insulin Degludec/Liraglutide (Xultophy®)
Insulin Glargine/Lixisenatide (Soliqua®)
Liraglutide (Victoza®)
Lixisenatide (Adlyxin™)
Metformin ER (Fortamet®, Glumetza®)
Semaglutide Injection (Ozempic®)
Semaglutide Oral (Rybelsus®)

CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS: (must meet all of the following)

- ~~Medication must be prescribed within an FDA-approved age range (outlined in table 1).~~
- ~~Patient must have a diagnosis of Type 2 Diabetes.~~
- ~~Patient must have HbA1c above 6.5%~~
- ~~Patient must have experienced an inadequate response after a trial of a preferred metformin ER agent at a maximum tolerated dose, OR have a documented intolerance or contraindication to metformin ER.~~
- ~~Prescriber must attest to all medication and/or class-specific safety criteria (outlined in table 1) as it applies to the medication requested.~~

Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.

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- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide a prespecified HbA1c goal of one of the following: 6.5%, 7.0%, or 8.0%.[1]
- For **Metformin ER (Fortamet®, Glumetza®)**, the patient must have had an adequate trial of generic metformin ER (Glucophage XR® equivalent) for at least 90 consecutive days of therapy in the past 120 day period.
- Patient must meet one of the following:
    - For **glycemic control** (must meet all of the following):
        - Patient must have a baseline HbA1c greater than the prespecified goal.
        - For HbA1c ≥10% or glucose level ≥300mg/dL, it is recommended (but not required) to initiate patients on an injectable therapy such as a GLP-1 RA or basal insulin.[1]
        - Patient must have had an adequate trial of generic metformin IR or metformin ER (Glucophage XR® equivalent) for at least 90 consecutive days of therapy in the past 120 day period, OR have a contraindication to metformin.[1,2]
    - For **cardiovascular disease** or **chronic kidney disease** (SGLT2 inhibitors, GLP-1 receptor agonists, and SGLT2 or GLP-1 combination products with FDA indication for cardiovascular disease or chronic kidney disease (Table 1):
        - Patient must meet one of the following:[1]
            - History of clinical atherosclerotic cardiovascular disease (ASCVD) defined as having at least one of the following diagnoses:
                - Coronary heart disease
                - Cerebrovascular disease (e.g. stroke, transient ischemic attack)
                - Peripheral arterial disease
                - Acute coronary syndromes (e.g. myocardial infarction, unstable angina)
                - Arterial revascularization (e.g. coronary artery bypass graft)
            - Diagnosis of chronic kidney disease
            - Diagnosis of heart failure
            - Indicators of high risk of developing ASCVD defined as:
                - Age ≥ 55 years with coronary, carotid or lower extremity artery stenosis > 50%
                - Left ventricular hypertrophy (LVH)

LENGTH OF APPROVAL (INITIAL) FOR GLYCEMIC CONTROL: 6 months
LENGTH OF APPROVAL (INITIAL) TO REDUCE THE RISK OF CV EVENTS AND ESKD: 12 months

CRITERIA FOR RENEWAL FOR ALL PRODUCTS: (must meet one of the following)

~~D~~For glycemic control, documented improvement of HbA1c from pretreatment levels, defined by one of the following:

- Reduction of HbA1c of at least 1% since the last approval.
- Achievement or maintenance of therapeutic HbA1c goal~~s (HbA1c ≤ 6.5%)~~ as specified on the initial request.

LENGTH OF APPROVAL (RENEWAL):

- 12 months if the patient is at HbA1c goal or for certain populations listed above using agents with proven benefits of cardiovascular disease, heart failure, or kidney disease.
- 6 months if the patient is not at goal, but has at least a 1% further reduction in HbA1c since the last approval.~~.~~

DRAFT PA Criteria

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved indications, age and dosing limits for Type 2 Diabetes Mellitus (T2DM) Agents.[3-24]

Agents	Indication(s)	Age	Dosing Limits
Biguanides			
Metformin ER (Fortamet®, Glumetza®)	Management of type 2 diabetes mellitus when hyperglycemia cannot be managed with diet and exercise alone.	≥ 17 years	2,000 mg/day
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists			
Dulaglutide (Trulicity®)	Adjunct to diet and exercise to improve glycemic control in type 2 diabetes mellitus (T2DM) (noninsulin dependent) Risk reduction of major cardiovascular (CV) events in adults with T2DM and established CV disease	≥ 18 years	1.5 mg SQ weekly
Exenatide (Bydureon®, Bydureon® BCise)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	2 mg SQ weekly
Exenatide (Byetta®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	10 mcg SQ twice daily
Liraglutide (Victoza®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of major cardiovascular (CV) events in adults with T2DM and established CV disease	≥ 10 years	1.8 mg SQ once daily
Lixisenatide (Adlyxin™)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	20 mcg SQ once daily
Semaglutide (Ozempic®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of major CV events in adults with T2DM and established CV disease	≥ 18 years	1 mg SQ once weekly
Semaglutide (Rybelsus®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	14 mg orally once daily
Long-Acting Insulins/Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists			
Insulin Degludec/ Liraglutide (Xultophy®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	50 units/1.8 mg SQ once daily
Insulin Glargine/ Lixisenatide (Soliqua®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	60 units/20 mcg SQ once daily
Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors – Single Agents			
Canagliflozin (Invokana®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	300 mg orally once daily

	Risk reduction of major CV events in adults with T2DM and established CV disease Risk reduction of end-stage kidney disease (ESKD), doubling of serum creatinine, CV death, and hospitalization for heart failure in adults with T2DM and diabetic nephropathy with urinary albumin excretion >300 mg/day		
Dapagliflozin (Farxiga®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of hospitalization for heart failure in patients with T2DM and established CV disease or multiple CV risk factors or multiple cardiovascular risk factors Reduce the risk of CV death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV) in those without T2DM	≥ 18 years	10 mg orally once daily
Empagliflozin (Jardiance®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of CV mortality in adults with T2DM and established CV disease	≥ 18 years	25 mg orally once daily
Ertugliflozin (Steglatro™)	Adjunct to diet and exercise to improve glycemic control in T2DM	≥ 18 years	15 mg orally once daily
Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors – Combination Agents			
Canagliflozin/Metformin (Invokamet®, Invokamet® XR)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of CV events in adults with T2DM and established CV disease Risk reduction of ESKD, doubling of serum creatinine, CV death, and hospitalization for heart failure in adults with T2DM and diabetic nephropathy with urinary albumin excretion >300 mg/day	≥ 18 years	300 mg/2,000 mg orally per day
Dapagliflozin/Metformin (Xigduo XR®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of hospitalization for heart failure in patients with T2DM and established CV disease or multiple CV risk factors or multiple cardiovascular risk factors	≥ 18 years	10 mg/2,000 mg orally once per day
Dapagliflozin/Metformin/ Saxagliptin (Qternmet XR®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	10 mg/2,000 mg/5 mg orally once per day

Dapagliflozin/Saxagliptin (Qtern®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	10 mg/5 mg orally once per day
Empagliflozin/Linagliptin (Glyxambi®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of CV mortality in adults with T2DM and established CV disease	≥ 18 years	25 mg/5 mg orally once per day
Empagliflozin/Linagliptin/ Metformin (Trijardy XR®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) Risk reduction of CV mortality in adults with T2DM and established CV disease	≥ 18 years	25 mg/5 mg/2,000 mg orally per day
Empagliflozin/Metformin (Synjardy, Synjardy XR®)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	25 mg/2,000 mg orally per day
Ertugliflozin/Metformin (Segluromet™)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	15 mg/2,000 mg orally per day
Ertugliflozin/Sitagliptin (Steglujan™)	Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)	≥ 18 years	15 mg/100 mg orally once per day

~~Table 1. Medication and class-specific safety criteria~~

MEDICATIONS/CLASSES	AGE (YEARS)	MEDICATION/CLASS-SPECIFIC SAFETY CRITERIA
SGLT2 Inhibitor Single Agents and Combinations		
Farxiga® (dapagliflozin)	≥18	- Patient does NOT have a diagnosis of type 1 diabetes - Patient must have a eGFR above: o 45 mL/min/1.73m2 ▪ Glyxambi, Invokamet, Invokamet XR, Invokana, Jardiance, Qtern, Synjardy, Syndardy XR o 60 mL/min/1.73m2 ▪ Farxiga, Steglatro, Steglujan, Segluromet Xigduo XR - Patient does NOT have any of the following contraindications: o End-stage renal disease o Currently on dialysis
Glyxambi® (Empagliflozin/linagliptin)	≥18	
Invokamet®, Invokamet XR® (Canagliflozin/metformin)	≥18	
Invokana® (canagliflozin)	≥18	
Jardiance® (empagliflozin)	≥18	
Qtern® (Dapagliflozin/saxagliptin)	≥18	
Segluromet™ (Ertugliflozin/metformin)	≥18	
Steglatro™ (ertugliflozin)	≥18	
Steglujan™ (Ertugliflozin/sitagliptin)	≥18	
Synjardy®, Synjardy XR® (Empagliflozin/metformin)	≥18	
Xigduo XR® (Dapagliflozin/metformin)	≥18	

~~Table 1 (cont.). Medication and class-specific safety criteria~~

MEDICATIONS/CLASSES	AGE (YEARS)	MEDICATION/CLASS-SPECIFIC SAFETY CRITERIA

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DRAFT PA Criteria

GLP-1 Receptor Agonists		
Adlyxin™ (Lixisenatide)	≥18	- For Bydureon, Bydureon BCise, Byetta, Ozempic, Tanzeum, Trulicity and Victoza o Patient does NOT have a history or family history of medullary thyroid carcinoma in the past 2 years o Patient does NOT have a history of multiple endocrine neoplasia syndrome type 2 in the past 2 years
Byetta® (Exenatide)	≥18	
Bydureon®, Bydureon® BCise™ (Exenatide ER)	≥18	
Ozempic® (Semaglutide)	≥18	
Tanzeum® (Albiglutide)	≥18	
Trulicity® (Dulaglutide)	≥18	
Victoza® (Liraglutide)	≥18	
Long-Acting Insulin/GLP1 Agonist Combinations		
Soliqua® (Insulin glargine/lixisenatide)	≥18	- Patient is inadequately controlled on: o For Soliqua – basal insulin (≤ 60 units daily) or lixisenatide o For Xultophy – basal insulin (≤ 50 units daily) or liraglutide - Patient does NOT have any of the following: o End stage renal disease (ESRD) o History of pancreatitis o Diabetic ketoacidosis or type 1 diabetes mellitus o Gastroparesis o Using prandial (meal-time) insulin o
Xultophy® (Insulin degludec/liraglutide)	≥18	

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Notes:

- The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when HbA1C levels (>10% [86 mmol/mol]) or blood glucose levels (>300 mg/dL [16.7 mmol/L]) are very high.[1]

References:

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20. Trijardy XR (empagliflozin, linagliptin, and metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; April 2020.
21. Synjardy (empagliflozin/metformin) Synjardy XR (empagliflozin/metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; January 2020.
22. Steglatro (ertugliflozin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; January 2020.
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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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